

REMARKS

Claims 1-19 are pending in the application and have been rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses the grounds of this rejection.

The application has three sets of claims based on three independent claims. Claim 1 is directed to an extract from a bacterium isolated from the skin of an animal. Claim 10 is directed to a bacterial isolate from a group of specifically identified bacteria. Claim 12 is directed to a method of identifying biologically active extracts, fractions or compounds from the bacteria identified in claim 10. The methodologies for identifying and isolating the extracts and bacterial isolates recited in the claims are clearly and completely described in the specification of the present application. Those skilled in the art can easily follow the teachings of the specification and identify the extracts and bacterial isolates recited in the claims.

To the best of applicant's knowledge, there is no prior art teaching of an extract from a bacterium isolated from the skin of an organism that at least partially respire through its skin which has activity against the growth of bacteria, fungi, viruses, or tumors. With regard to claims 1-8 and 13-19, the Examiner states that: "First, it is noted that the bacteria are only identified by a subjective series of numbers, which contain no information as to the source of the bacteria or any identifying characteristics of the bacteria." This statement ignores the basic teaching of the application which is that the bacteria are isolated from the skin of organisms that respire at least partially through their skin, including salamanders, frogs, certain fish, and the like. Therefore, there is clear identification of the source of the bacteria. The specification describes in sufficiently complete detail the organisms from which the bacteria were isolated and the method of identification and isolation of these bacteria as to enable those skilled in the art to practice the invention recited in claim 1.

The Examiner also states that no taxonomic characterization of the bacteria is included nor is there DNA-DNA hybridization rRNA analyses. Applicant does not dispute this assertion. However, applicant vigorously disputes that such information is required in order to support the present claims of the application. It is not necessary for a practitioner to know the taxonomic or genotypic information, much less the DNA-DNA hybridization or rRNA information, of the bacteria from which the claimed extracts are isolated in order to follow the methodologies taught fully in the specification and to thereby become possessed of extracts which function as recited

in claims 1-8 and 13-19. The primary screening process described in the patent application represents a well-known and much utilized procedure for determining the presence of bacteria that are capable of producing antimicrobial compounds. Screening for the presence of such bacterial isolates for potential sources is the norm in pharmaceutical laboratories across the world. "The classic approach to find new antibiotic-producing strains of bacteria has been to screen large number of isolates from soil samples for microorganisms that naturally produce antimicrobial substances." Atlas, R.M. 1995. Microorganisms in Our World. Mosby Publishers, St. Louis Missouri, p. 718. Further, the technologies described that were used to determine the ability of the isolates to produce antimicrobial compounds are well known (see Alcamo 1994). The inventions of claims 1-8 and 13-19 are broader than specific bacteria, albeit specific bacteria are identified in the application.

The Examiner states, in Paragraph 4, that undue experimentation would be required in order to screen bacteria from the skin of amphibians given the 3% success rate in finding a bacterium that fulfills the requirements of the claims. Applicant respectfully disagrees. A 3% success rate is extremely high given the likelihood of finding isolates in other sources, notably soil, where the success rate is somewhere in the range of 1 in 400,000. The methodology taught in the specification is repeatable and successful and is not unduly time-consuming nor complicated. It can easily be practiced by those skilled in the art to achieve the isolates called for in the claims. The rejections of the claims under 35 U.S.C. Section 112, first paragraph, should be reconsidered and withdrawn.

Applicant believes that no deposit of microorganisms is necessary in order to satisfy Section 112. However, Applicant has identified and maintained the bacterial isolates of the preferred embodiments and is prepared to make a patent deposit and to supplement the written description, if necessary.

Accordingly, the purpose of the claimed invention is not taught nor suggested by the cited references, nor is there any suggestion or teaching which would lead one skilled in the relevant art to combine the references in a manner which would meet the purpose of the claimed invention. Because the cited references, whether considered alone, or in combination with one another, do not teach nor suggest the purpose of the claimed invention, Applicant respectfully submits that the claimed invention, as amended, patentably distinguishes over the prior art, including the art cited merely of record.

Based on the foregoing, Applicant respectfully submits that its claims 1-19 are in condition for allowance at this time, patentably distinguishing over the cited prior art. Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to call the undersigned attorney at (515) 288-2500 to discuss any remaining issues that may exist or arise.

Respectfully submitted,

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